AMENDMENTS TO THE CLAIMS

Please cancel Claims 2, 3, 9, 10 and amend Claims 1, 4-8, and 11-14 as follows:

1. (Currently amended) A method for creating a customized clinical trial database management system for use in conducting a clinical trial, the method comprising:

providing a user with at least one question related to an anticipated use of the customized database management system, wherein the anticipated use comprises administration of a clinical trial;

receiving at least one answer to the at least one question from the user;

retrieving a set of clinical trial governance rules that govern the management of data acquired during a clinical trial ~~associated with the anticipated use of the customized database management system~~;

analyzing the at least one answer and the set of clinical trial governance rules; and

generating the customized clinical trial database management system according to the analyzing of the at least one answer and the set of clinical trial governance rules, whereby the generated clinical trial database management system is configured to govern the conduct of a clinical trial and to manage data acquired during the clinical trial.

2. (Canceled)

3. (Canceled)

4. (Currently amended) The method for creating a clinical trials database management system of claim ~~3~~1 wherein the set of clinical trial governance rules is derived from clinical trials regulations.

5. (Currently amended) The method for creating a clinical trials database management system of claim 1 wherein the set of clinical trial governance rules governs the at least one answer.

6. (Currently amended) The method for creating a clinical trials database management system of claim 5 wherein the generating creates a customized database management system that is in conformance with the set of clinical trial governance rules and the at least one answer.

7. (Currently amended) The method for creating a clinical trials database management system of claim 1 wherein the providing a user with at least one question, the receiving at least one answer, the retrieving a set of clinical trial governance rules, the analyzing, and the generating are all performed on a common Web site.

8. (Currently amended) A creation system for generating a customized database management system used to conduct a clinical trial, the creation system comprising:

a computer configured to execute a first routine for asking a user at least one question related to a desired application for the customized clinical trial database management system and for receiving at least one answer to the at least one question from the user;

the computer further configured to execute a second routine for retrieving a set of clinical trial governance rules that govern the management of data during a clinical trial ~~associated with the desired application for the customized database management system~~;

the computer further configured to execute a third routine for processing an analysis of the at least one answer and the set of clinical trial governance rules; and

the computer further configured to execute a fourth routine for generating the customized clinical trial ~~relational~~ database management system according to the analysis.

9. (Canceled.)

10. (Canceled.)

11. (Currently amended) The creation system of claim ~~10~~8 wherein the set of rules is in conformance with clinical trials regulations.

12. (Currently amended) The creation system of claim ~~10~~8 wherein a generated customized clinical trial database management system is in conformance with the set of rules and the at least one answer.

13. (Currently amended) The creation system of claim ~~10~~8 wherein the asking and receiving are handled by a dialogue box described by software executed by the computer.

14. (Currently amended) The creation system of claim ~~10~~8 wherein the first routine, second routine, third routine, and fourth routine reside at a common Web site.

15. (Original) A method for creating a clinical trials database management system, the method comprising:

providing information descriptive of a particular clinical trial;

providing a first set of rules in accordance with clinical trials governing regulations;

generating a second set of rules that conforms to the information and to the first set of rules; and

generating the clinical trials database management system to be compliant with the second set of rules.

16. (Original) The method of claim 15 wherein the clinical trials database management system is contained within a Web site.

17. (Original) The method of claim 16 wherein the clinical trials database management system is operable on the Web site.

18. (Original) The method of claim 15 wherein the information descriptive of a particular clinical trial includes a user name, and data collection specifications.

19. (Original) The method of claim 18 wherein the information descriptive of a particular clinical trial further includes specifications for data cleaning.

20. (Currently amended) Computer-readable storage media containing computer software that performs the following functions when loaded into and executed on a computer:

presents to a user a question related to ~~a desired application for a~~ use of a customized database management system for conducting a clinical trial;

receives from the user an answer to the question;

retrieves a set of clinical trial governance rules associated with managing data during a clinical trial ~~the desired application for the customized database management system~~;

analyzes the answer and the set of clinical trial governance rules; and

generates the customized clinical trial relational database management system according to the analysis.

21. (New) A method for creating and a customized clinical trial database management system and subsequently using it to conduct a clinical trial, the method comprising:

providing a user with at least one question related to administration of a particular clinical trial;

receiving at least one answer to the at least one question from the user;

retrieving a set of clinical trial governance rules derived from clinical trial regulations and associated with conducting clinical trials;

analyzing the at least one answer and the set of clinical trial governance rules;

generating the customized clinical trial database management system according to the analyzing of the at least one answer and the set of clinical trial governance rules; and

using the customized clinical trial database management system to manage data during a clinical trial in accordance with the clinical trial governance rules.

22. (New) The method of claim 21 wherein the use of the customized clinical trial database management system comprises collecting data during trials of a new product and entering the collected data into the customized clinical trial database management system.